K123663

510(k) Summary

Liquichek Cardiac Markers Plus Control LT

DEC 2 7 2012

1.0 **Submitter**

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
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Contact Person

Suzanne Parsons
Regulatory Affairs Manager
Telephone: (949) 598-1467

Date of Summary Preparation

December 20, 2012

2.0 **Device Identification**

Product Trade Name:	Liquichek Cardiac Markers Plus Control LT
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Liquichek Cardiac Markers Plus Control LT
Bio-Rad Laboratories
Irvine, California

510 (k) Number: K050537

4.0 **Description of Device**

Liquichek Cardiac Markers Plus Control LT is prepared from human serum with added constituents of human and animal origin, chemicals, preservatives and stabilizers. The control is provided in liquid form for convenience.

5.0 **Value Assignment**

The mean values and the corresponding ±3SD ranges printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product. It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

6.0 Intended Use

Liquichek Cardiac Markers Plus Control LT is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

7.0 Comparison of the new device with the Predicate Device

Liquichek Cardiac Markers Plus Control LT claims substantial equivalence to the Liquichek Cardiac Markers Plus Control LT currently in commercial distribution (K050537). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1: Similarities and Differences between the new and predicate device

Characteristics	Liquichek Cardiac Markers Plus Control LT (New Device)	Liquichek Cardiac Markers Plus Control LT (Predicate Device, K050537)
	Similarities	
Intended Use	This product is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	This product is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.
Form	Liquid	Liquid
Matrix	Human serum	Human serum
	Differences	
Fill Volume	2.5 mL	3 mL
Thawed and Unopened	10 days at 2 - 8 °C	None
Thawed & Opened	10 days at 2 - 8 °C	20 days at 2 - 8 °C except for: NT-proBNP: 15 days TnI : 10 days TnT: 4 days
Storage Unopened (Shelf life)	At -20 to -50 °C until the expiration date	At -20 to -70 °C until the expiration date
Frozen aliquot	None	30 days at -20 to -70 °C
Analytes	**Contains:** Troponin I Creatine Kinase, Total (CK Total) CK-MB Isoenzyme Digitoxin C-Reactive Protein(CRP) Myoglobin N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) **Does not contain:** Troponin T Homocysteine BNP	**Contains:** Troponin I Creatine Kinase, Total (CK Total) CK-MB Isoenzyme Digitoxin C-Reactive Protein(CRP) Myoglobin N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) Troponin T Homocysteine BNP (Not listed in the insert)

8.0 Statement of Supporting Data

Real-time stability studies were conducted to establish the thawed stability claims (open-vial and unopened). Accelerated stability studies were conducted to establish the shelf-life claims at -20 to -50 °C. Based on the available data, product claims are as follows:

Thawed and Opened:	10 days at 2 to 8°C
Thawed and Unopened:	10 days at 2 to 8°C
Shelf Life Stability:	32.5 months at -20 to -50°C

9.0 Conclusion

Based on the performance characteristics indicated above, the Bio-Rad Liquichek Cardiac Markers Plus Control LT is substantially equivalent to the predicate device, k050537.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 27, 2012

Bio-Rad Laboratories
c/o Suzanne Parsons
9500 Jeronimo Road
Irvine, CA 92618-2017

Re: k123663
Trade/Device Name: Liquichek Cardiac Markers Plus Control LT
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: November 26, 2012
Received: November 28, 2012

Dear Ms. Suzanne Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Denise Johnson-lyles -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123663

Device Name: **Liquichek Cardiac Markers Plus Control LT**

Indications for Use:

Liquichek Cardiac Markers Plus Control LT is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

Prescription Use X And/Or Over the Counter Use ___.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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